REMARKS

Applicant thanks the Examiner for the interview on June 5, 2003, with the undersigned and Mark Newman. Applicant believes that the interview was helpful in advancing prosecution of this matter. In the interview, the claims were discussed and the subject matter was distinguished from the prior art of record. Possible claim amendments were discussed.

Claim 1 was amended to include language that the Examiner believed to be clearer with respect to the integration of the collagen matrix. Claim 36 has been amended similarly. It is noted that independent claim 27 already requires integration of the collagen matrix. New claim 44 specifies that the collagen matrix layer is a sheet of collagen matrix material having a three-dimensional structure which, upon placement into a wound, supports tissue remodeling. Support for new claim 44 is found in the specification, particularly page 1, lines 24-26 and page 7, lines 20-30. New claim 45 specifies that the collagen matrix layer is selected from the group consisting of submucosa, lamina propria, and stratum compactum. Support for new claim 45 is found on page 2, lines 1-8.

Claims 1-2, 8-9, 14-18, 27-28, 30-37, and 39-43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,645,081 to Argenta in view of U.S. Patent No. 5,759,570 to Arnold. According to the Examiner, Argenta teaches a method of treating tissue damage in burns and wounds. The apparatus of Argenta comprises a vacuum means for creating a negative pressure on the area of tissue surrounding the wound, sealing means operatively associated with the vacuum means to maintain negative pressure on the wound, and a screen means to prevent overgrowth of tissue in the wound area. The screen means comprises a section of open-cell foam, which is porous and configured to be placed over the wound into which is inserted a flexible tube for attachment to a suction pump. The screen means is a semi-rigid structure and is directly connected to the vacuum source. The Examiner acknowledges that Argenta lacks a collagen layer in contact with the wound.

According to the Examiner, Arnold teaches a multilayer wound dressing for the treatment of damaged, burned, ulcerated, or otherwise traumatized mammalian skin. The wound dressing of Arnold comprises a wound contacting layer comprising a bioabsorbable and hydrophilic polymeric material such as collagen. The wound contact layer is attached to a molecular filtration membrane, which is liquid permeable of defined pore size. An absorbent layer on top of the molecular filtration membrane further absorbs the wound

exudates through the membrane. The wound dressing of Arnold is held in place by a final protective covering.

In the Office Action, the Examiner found that the wound contacting layer of Arnold is similar to the claimed collagen matrix. The Examiner also finds that the absorbent layer reads on the currently claimed structure of paragraph (c) of claim 1. Thus, the Examiner concludes that it would have been obvious for one of ordinary skill in the art to add a collagen wound contact layer of Arnold in the vacuum assisted therapy of Argenta.

As the Examiner has noted in the interview summary, the wound contacting layer of Arnold is not analogous to the presently claimed collagen matrix for placement on and integration into a wound. With respect to Arnold's wound contacting layer, rather than integration, Arnold teaches removal of this layer. For example, on col. 4, lines 63-66, Arnold teaches that "[t]he layer of wound-friendly gel prevents the wound contact part of the dressing from adhering to the wound, and so makes removing and replacing the wound dressing very easy and non-traumatic." Also, as noted by the Examiner, Arnold teaches that the wound contact layer may be attached to the molecular filtration membrane (col. 5, lines 39-48) which is removed upon dressing changes, and the "wound dressing is comfortable, absorbent and easy to replace with minimal wound trauma." (Col. 7, lines 17-18).

To the contrary, as discussed at page 7, lines 17-19 and page 11, lines 7-14 of the present specification, the collagen layer of the present invention becomes integrated in the wound and is restructured to resemble the surrounding tissue. All claims of the present invention require a collagen matrix that is integrated into the wound. If the wound contact layer is provided integrally with the rest of the multilayered wound dressing, as taught by Arnold, and integration into the wound were to occur, removal of the wound dressing would result in the creation of a new wound. As Arnold teaches removal of the dressing with minimal trauma (col. 4, lines 63-66; col. 7, line 18), Arnold clearly does not teach integration of the wound contact layer into the wound. That the wound contact layer may be made of biodegradable material, including collagen, is of no moment. The biodegradable material is provided to deliver active agents to the wound, and any remaining material would be removed with minimal trauma upon removal of the bandage. Clearly, Arnold does not teach integration of a collagen matrix into a wound.

A person of ordinary skill in the art at the time this invention was made simply would not have combined the teachings of Argenta with the teachings of Arnold to arrive at the present invention. Argenta teaches that healing occurs at a faster rate with only reduced pressure and placing the screen means in the wound. Arnold teaches a multilayer wound

dressing having a wound contacting layer that may comprise collagen. The wound contacting layer is provided to make removal of the dressing very easy and non-traumatic. Neither reference teaches a collagen matrix for placement on and integration into the wound. Thus, the combination of Argenta and Arnold would not have resulted in the presently claimed invention.

Furthermore, applicant respectfully submits that the device of Arnold is incompatible with the device taught by Argenta. The device of Arnold includes a molecular filtration membrane having particularly small pore sizes. The molecular filtration membrane retains high molecular weight components at the wound site, while allowing aqueous liquids to wick rapidly across the membrane. Arnold also teaches that the absorbent layer may be provided with active ingredients to diffuse back through the molecular membrane. Application of vacuum to the device of Arnold would prevent this reverse diffusion and may result in fairly rapid clogging of the membrane with the high molecular weight components. Applicant respectfully submits that the devices of Argenta and Arnold would have been incompatible.

Finally, the collagen matrix of the present invention is a different material from the collagen gel of Arnold. The present collagen matrix provides a three-dimensional support for cell infiltration and remodeling (page 1, lines 24-26). Necessarily, the collagen matrix of the present invention withstands the forces of vacuum sufficiently to be integrated into the wound. The gel of Arnold is not such a scaffold structure. New claim 44 has been added to clarify this distinction.

Accordingly, applicant respectfully requests withdrawal of this rejection.

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,645,081 to Argenta in view of U.S. Patent No. 5,759,570 to Arnold as applied to claims 1-2, 8-9, 14-18, 27-28, 30-37, and 39-43, and further in view of U.S. Patent No. to Wadstrom. According to the Examiner, Wadstrom teaches treatment compositions comprising fibrin or fibrinogen for wound healing.

While applicant acknowledges that Wadstrom teaches that fibrin sealants may be used for wound healing, Wadstrom fails to overcome the deficiencies discussed above, with respect to Argenta and Arnold. Accordingly, applicant respectfully requests withdrawal of this rejection.

CONCLUSION

The application is believed to be in condition for allowance. Withdrawal of the rejection and passage of the application to issuance is respectfully requested.

Respectfully submitted,
BARNES & THORNBURG

Jill T. Powlick
Attorney Registration No. 42,088

JTP:jdh
Indianapolis, IN 46204
(317) 231-7504

IND502 JTP 587772v1